

Scientific & Regulatory Consultants, Inc.

June 15, 2021

Ms. Stacey Grigsby, PM 34
US Environmental Protection Agency
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

VIA CDX

Dear Ms. Grigsby,

SUBJECT: Application for New End-Use Product Registration of Honey Cake, EPA Reg. No. 777-XXX
Including New Use of AD Non-Food Active Ingredient

Scientific & Regulatory Consultants, Inc. (SRC) is submitting an application for registration of subject product on behalf of Reckitt Benckiser LLC (Reckitt). Per the outcome of the Honey Cake pre-submission meeting (May 24, 2021) this application for a new end-use product contains an increased level of active ingredient than existing AD registrations. It is submitted as a PRIA Code A500, new use of an existing non-food active ingredient, which has a 12-month review period and PRIA fee of \$33,506. (Proof of payment via www.pay.gov is included.) The Agency did agree, however, to expedite review of this submission to 9 months.

End-Use Product Description

As described in the pre-submission meeting, Honey Cake is an aerosol air sanitizer and treatment, primarily for residential use, with public health claims including viruses as a response to the COVID-19 pandemic. A related public health organisms protocol submission is currently under internal review via its own PRIA application. The Agency agreed in the meeting to the submission of available data prior to efficacy completion to allow for the new use assessment to get underway.

Active Ingredient Source

Honey Cake will be made with an unregistered source of active ingredient (Dipropylene glycol, PC 068604), as indicated on the enclosed Confidential Statements of Formula (CSFs) and written product chemistry. The TGA data requirements are met as outline on the enclosed Data Matrix, including an Offer to Pay Data Citation for a selective cite-all of which a sample letter is enclosed. Additionally, supplemental discussion volumes are provided to describe the typical end use product (Honey Cake).

Product Chemistry

This submission provides the Confidential Statements of Formula (CSFs), available written product chemistry, and the EPA Form 8570-36 summarizing the physical chemical characteristics for this product. GLP studies are in progress to complete the Part A and Part B Chemistry data requirements and will be submitted as they become available. A registrant fragrance certification is enclosed as well as certifications from the fragrance houses indicating they are compliant with the Fragrance Ingredients List (FIL).

Acute Toxicology

An executive summary for the overall Acute Toxicity classifications for Honey Cake is submitted, in addition to a volume for each of the acute data points. The proposed label reflects these conclusions. The GLP studies are in progress and we anticipate submitting by October.

Efficacy

Efficacy will be conducted in accordance with the protocol resulting from the separate PRIA protocol review action. Upon complete of the data set for each organism, studies will be submitted for review starting in August under the Honey Cake application. The proposed label reflects the anticipated label claims and uses.

Reckitt is committed to providing additional studies and information as it becomes available. In the interim we look forward to Agency input and working together to achieve this new claim set. For questions or clarification, please contact me as soon as possible at 260-244-6270 or rmannion@srcconsultants.com. The same email should be used for all tracking milestone emails.

Sincerely,



Rebecca Mannion
Agent